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| APPLICATION NO.                                | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |  |
|--|-------------|----------------------|---------------------|------------------|--|--|
| 10/602,797 06/24/2003                          |             | Thomas May           | 022956-0217         | 1008             |  |  |
| 21125 7590                                     | 07/25/2006  |                      | EXAM                | EXAMINER         |  |  |
| NUTTER MCCLENNEN & FISH LLP                    |             |                      | BROWN, MICHAEL A    |                  |  |  |
| WORLD TRADE                                    | CENTER WEST |                      |                     |                  |  |  |
| 155 SEAPORT BOULEVARD<br>BOSTON, MA 02210-2604 |             |                      | ART UNIT            | PAPER NUMBER     |  |  |
|  |             |                      | 3764                |                  |  |  |

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |  | Amplicatio   | - No  | Amplian mate)  |        |  |  |  |
|--|--|--|---|--|--------|--|--|--|
|  |  | Applicatio   |   | Applicant(s)   |        |  |  |  |
| Office Action Summary  |  | 10/602,79  | 7<br>   | MAY, THOMAS  |        |  |  |  |
| Office A   | Cuon Summary   | Examiner   |   | Art Unit   |        |  |  |  |
| 71 000 11 101  | DATE (4)   | Michael Br   |   | 3764   |        |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |   |  |        |  |  |  |
| WHICHEVER IS LC  - Extensions of time may be after SIX (6) MONTHS from the second for reply is second for reply is second for reply within the second for reply received by the second for reply reply | ATUTORY PERIOD FOR FONGER, FROM THE MAILII e available under the provisions of 37 of mm the mailing date of this communication pecified above, the maximum statutory set or extended period for reply will, by office later than three months after the truent. See 37 CFR 1.704(b). | NG DATE OF TH<br>CFR 1.136(a). In no eve<br>ion.<br>period will apply and will<br>statute, cause the appli | IS COMMUNICATION  nt, however, may a reply be tim  expire SIX (6) MONTHS from cation to become ABANDONE | N. nely filed the mailing date of this or D (35 U.S.C. § 133). |        |  |  |  |
| Status   |  |  |   |  |        |  |  |  |
| 1) Responsive to   | communication(s) filed on  | 04 May 2006.   |   |  |        |  |  |  |
| 2a) This action is   | This action is <b>FINAL</b> . 2b) This action is non-final.  |  |   |  |        |  |  |  |
| 3) Since this app  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |   |  |        |  |  |  |
| closed in acco   | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |   |  |        |  |  |  |
| Disposition of Claims  |  |  |   |  |        |  |  |  |
| 4)⊠ Claim(s) <u>1-30</u>   | is/are pending in the applic   | cation.  |   |  |        |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |  |   |  |        |  |  |  |
| 5) Claim(s)  | 5) Claim(s) is/are allowed.  |  |   |  |        |  |  |  |
| 6)⊠ Claim(s) <u>1-30</u>   | •  |  |   |  |        |  |  |  |
| ·  | _ is/are objected to.  |  |   |  |        |  |  |  |
| 8) Claim(s)  | are subject to restriction   | and/or election re   | equirement.   |  |        |  |  |  |
| Application Papers   |  |  |   |  |        |  |  |  |
| 9) The specificati   | on is objected to by the Exa   | aminer.  |   |  |        |  |  |  |
| 10)☐ The drawing(s   | ) filed on is/are: a)[   | accepted or b)[  | $\square$ objected to by the I  | Examiner.  |        |  |  |  |
| Applicant may  | not request that any objection   | to the drawing(s) b  | e held in abeyance. See   | e 37 CFR 1.85(a).  |        |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |  |   |  |        |  |  |  |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |  |   |  |        |  |  |  |
| Priority under 35 U.S.   | C. § 119   |  |   |  |        |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |  |  |   |  |        |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |  |  |   |  |        |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |  |   |  |        |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |  |  |   |  |        |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |  |   |  |        |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |  |  |   |  |        |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |  |   |  |        |  |  |  |
|  |  |  |   |  |        |  |  |  |
| Attachment(s)  |  |  |   |  |        |  |  |  |
| 1) Notice of References (2) Notice of Draftsperson   | Cited (PTO-892)<br>'s Patent Drawing Review (PTO-94  | 48)  | 4) Interview Summary Paper No(s)/Mail Da  |  |        |  |  |  |
|  | Statement(s) (PTO-1449 or PTO/   |  | 5) Notice of Informal P 6) Other:   |  | O-152) |  |  |  |
|  |  |  |   |  |        |  |  |  |

### **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreyfuss in view of with Gogolewski, along with Sasso.

Dreyfuss discloses in figures 1-7 a tissue fixation device, comprising an elongated body 108, formed of a biocompatible material (page 3, section 0038, lines1-2), having an outer surface (fig. 5), a proximal end (fig. 5), a distal end (fig. 5), a longitudinal axis (fig. 5), an internal cavity 136, extending into the body forming an opening in the proximal end (fig. 5) of the body, the cavity terminating proximal to the distal end (fig. 5), at least one opening (117, 118) formed in the outer surface of the body, the opening is in fluid communication with the internal cavity (fig. 5), the body is a pin, a portion of the outer surface of the body includes surface features (threads 116), the outer surface is smooth (at the lower end), the outer surface of the elongated body is porous (at 117, 118) the openings (117, 118) communicate with the cavity through a passage 126, the outer surface is non-porous (the upper end away from 117, 118), the elongated body has a substantially cylindrical shape (fig. 1) and the distal end is tapered at 114. However, Dreyfuss doesn't disclose the elongated body being formed of a bioresorbable material. Gogolewski teaches in figures 1-5 tissue fixation device

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that is formed of a bioresorbable material that is a polymer that includes carprolactone and poly (amino acids), (col. 5, lines 5-22). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the biocompatible fixation device disclosed by Dreyfuss could be fabricated out of the type of polymers as taught by Gogolewski in order to allow the fixation device to degrade in the body over a period of time. The length of the body, the diameter of the pin, the resorption profile of the pin being in the range of about 0.5mm to 5mm, the range of the diameter of the pore, the range of the number of openings and the range of the diameter of the at least one opening are design choices that aren't critical. Thus, these dimension provided no novelty over the prior art. The treatment material and the biologically material are intended use that weren't positively claimed (in claims 1-24). As for claims 25-30, Dreyfuss discloses placing an adhesive on the ends of the graft 138. This adhesive could be injected into the channel or placed on the ends of the graft and inserted into the opening. However, Sasso provides a teaching for injecting an active material 88 into a fixation device 20 so the material flows through openings 32 in the fixation device. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the adhesive disclosed by Dreyfuss could be injected into the opening in order to used the adhesive to hold the graft in place. The different types of treatment material, the active material, the adhesive agent and the anchoring agent are old and well known in the surgical art. In order words, using either of these elements wouldn't involve and inventive step.

## Response to Arguments

Applicant's arguments filed May 4, 206 have been fully considered but they are not persuasive. Applicant argues that Dreyfuss teaches a suture anchor for anchoring sutures in bone that is made of biocompatible metal that isn't bioresorbable. The examiner concurs. On the other hand, if one of ordinary skill in the art wanted to allow the suture anchor to remain permanently in the body, yet eliminate the risk of causing harm to tissue, the suture anchor could be made of a bioresorbable material. Gogolewski teaches a tissue fixation device made of a bioresorbable material. Clearly, forming the suture anchor disclosed by Dreyfuss of a bioresrorbable material to allow it to absorb into the body is taught by Gogolewski. It is old and well known in the surgical fastener art to form a fastener of a bioresrorbable material to prevent a surgeon from having to operate on a patient and remove the fastener after the healing process is completed. Applicant agues that Dreyfuss or any of the other cited prior art doesn't disclose or suggest a tissue graft positioned in a portion of a bone tunnel and the fixation device inserted within the bone tunnel. However, independent claim 25, doesn't positively recite the method step of inserting a tissue graft in position in a portion of a bone tunnel. Thus, the prior art only has to be capable of performing this method step. Clearly a tissue graft can be inserted into the cavity disclosed by Dreyfuss. Afterwards the tissue graft and the fastener could be inserted into and fasten to the bone tunnel. Applicant argues that the prior art doesn't disclose the step of injecting a treatment material into the channel of a tissue fixation device. However, Sasso was used a modifier to provide a method step of inserting a treatment material into a cavity of a tissue fixation device.

### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 571-272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gergory Huson can be reached on 571-272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Brown July 21, 2006

> MICHAEL A. BROWN PRIMARY EXAMINER

Michael a. Brown